

## REMARKS

### I. Status

Claims 1-51 are pending in the application. Claims 1-17, 32-44, and 47-51 are withdrawn. Claim 18 is currently cancelled without prejudice and claims 19-30 and 45-46 are currently amended to depend from independent claim 31. New claims 52-55 are being added. Upon entry of the instant amendment, claims 19-31 and 45-46 and 52-55 currently are subject to prosecution on the merits.

Claim 31 is currently amended to facilitate prosecution of the instant application. Notably, the amendment to this claim further clarifies that the high dose pharmaceutical composition in unit dosage form comprises a therapeutically effective amount of clofarabine for the treatment of an autoimmune disorder, wherein the therapeutically effective amount of clofarabine is sufficiently high to treat the autoimmune disorder.

Claims 18-24 and 26-31 stand rejected under 35 U.S.C. § 102(b) over U.S. 5,384,310 ("Montgomery"). Claims 25 and 45-46 stand rejected under 35 U.S.C. § 103(a) over Montgomery.

### II. Claims 18-24 and 26-31 Are Novel

Claims 18-24 and 26-31 stand rejected under § 102(b) over Montgomery. The rejection of claim 18 and all claims previously dependent therefrom is now moot by virtue of the current amendment. Applicants traverse the rejection because Montgomery does not mention a high dose pharmaceutical composition in unit dosage form that is therapeutically effective for the treatment of an autoimmune disorder.

Amended claim 31 defines a high dose pharmaceutical composition in unit dosage form for the treatment of an autoimmune disorder comprising a therapeutically effective amount of

clofarabine, or a pharmaceutically acceptable salt, hydrate, clathrate, solvate, prodrug, metabolite or stereoisomer thereof and a pharmaceutically acceptable carrier, wherein the therapeutically effective amount of clofarabine is sufficiently high to treat the autoimmune disorder. As such, claim 31 requires clofarabine to be present in the pharmaceutical composition in an amount that is therapeutically effective for the treatment of an autoimmune disorder.

Montgomery does not explicitly mention clofarabine to be present in the pharmaceutical composition at a high dose in unit dosage form that is therapeutically effective for the treatment of an autoimmune disorder, and the Examiner does not indicate as such. At best, the Examiner merely mentions at page 3 of the Office Action how Montgomery indicates that clofarabine can be administered in a wide range of regimens ranging from about 10 mg to 1000 mg per day. This daily regimen mentioned by Montgomery is not necessarily a pharmaceutical composition in unit dosage form effective for the treatment of an autoimmune disorder. Thus, Montgomery does not explicitly or inherently anticipate claim 31.

Dependent claims 19-30, 45-46, and 52-55 are novel over Montgomery at least by virtue of their direct or indirect dependency from claim 31. As such, removal of the instant rejection is respectfully requested at this time.

### **III. Claims 25 and 45-46 Are Not Obvious**

Claims 25 and 45-46 stand rejected under § 103(a) over Montgomery. Applicants traverse this rejection at least because the Examiner has not satisfied the burden of establishing a *prima facie* case of obviousness. The Examiner's mere statement that what Montgomery does not mention, i.e., aerosols or gel compositions, would have been well within the purview of one of ordinary skill in the art at the time of the invention does not satisfy the Examiner's burden. M.P.E.P. § 2143.01 (8<sup>th</sup>

Ed., Rev. 6). Absent the Examiner establishing a *prima facie* case of obviousness against claims 25 and 45-46, such claims are deemed to be nonobviousness and an indication to that effect is respectfully requested at this time.

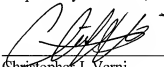
**IV. Conclusion**

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of all pending claims at this time. To the extent the Examiner believes that it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe that a fee is associated with the filing of this paper, which is detailed in a fee transmittal enclosed herewith. To the extent an additional fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 07-1074.

Respectfully submitted,

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